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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,859	05/29/2002	Seishi Kato	2002-0400 A	6799

  

EXAMINER	
SCHWADRON, RONALD B	

  

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 10/088,859	Applicant(s) KATO ET AL.	
	Examiner Ron Schwadron, Ph.D.	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1 and 2 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/13/07 has been entered.

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. The rejection of claims 1,2 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for the reasons elaborated in the previous Office Action is withdrawn in view of the amended claims.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. The rejection of claims 1 and 2 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the reasons elaborated in the previous Office Action is withdrawn in view of the amended claims.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1 and 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scholler et al. (US 2003/0008342) in view of Yokoyama-Kobayashi et al. Scholler et al. disclose immunization with vectors that induce antibodies wherein the vectors can encode a fusion protein with an artificially added transmembrane domain (see abstract, [0022], [0053]-[0055] and [0087], [0115]). Scholler et al. disclose immunization via intradermal administration (see Example 2). The antibody response is measured in an in vitro assay wherein the sample would be isolated and purified prior to or during the assay (see [0034] and [0142]). Scholler et al. do not disclose use of the vector recited in the claims using SEQ ID NO. 2 or that the antigenic protein is fused with the c terminal of a transmembrane domain. Yokoyama-Kobayashi et al. teach the vector recited in the claims (see Figure 1(b) for a description of the peptide encoded by the vector and pages 162, sections 2.2,2.3 and page 163, section 3.2 for a description of said vector). Said vector encodes a fusion protein containing an artificially added transmembrane domain wherein a protein is fused c-terminal to said transmembrane domain (see abstract). Yokoyama-Kobayashi et al. disclose that said vector can be used to produce a fusion protein that can be used to anchor a secreted molecule to the cell surface (see abstract). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Scholler et al. disclose immunization with vectors that induce antibodies wherein the vectors can encode a fusion protein with an artificially added transmembrane domain whilst Yokoyama-Kobayashi et al. teach a vector that encodes a fusion protein containing an artificially added transmembrane domain wherein a protein is fused c-terminal to said transmembrane domain.

Regarding applicants comments, Scholler et al. disclose that the SRA can be a secretory protein (see section [0021, line 9]). Regarding applicants comments about "concrete examples", "concrete examples" are not required to provide enablement for a US patent application or prior art reference. Applicant has not provided evidence as to why Scholler et al. is not enabled. Regarding Boyle et al., said reference is limited to studies using intramuscular injection (see abstract). Thus, said reference does not even address the response found in animals injected via other routes. The claims are not limited to a particular route of administration. Furthermore, Boyle et al. actually discloses **that the antibody response seen to mOVA versus sOVA depends on the time point examined and the responses are equivalent at the time of peak response** (see page 1900, first incomplete paragraph, lines 3-8 ). Boyle et al. disclose that:

*"Compared to the response to sOVA, the IgG response of mOVA immunized mice was 30 fold lower at 2 weeks, but when it peaked at 8 weeks there was no significant difference from that of sOVA immunized mice (Fig, 2A) although the response in the sOVA immunized mice had reached a plateau..".*

Furthermore, Boyle et al. disclose that:

*"The IgG2a and IgG2b titers were similar between sOVA and mOVA immunized mice at all time points. Similar results were obtained in CBAXC57Bl/6 mice (data not shown)."*  
(page 1900, second column).

Furthermore, regarding the applicability of the findings of Boyle et al. to other antigens, Boyle et al. disclose that other researchers have found only a "slight increase" in response to immunization with secreted versus membrane bound antigen (see page 1904, column 1, lines 9-15). Furthermore, Boyle et al. disclose that differences in the plasmids used could potentially account for the results that they describe (see page 1904, second column, first complete paragraph).

In addition, the Boyle et al. reference is drawn to i.m immunization, where the instant claims are not drawn to i.m immunization. Applicant comments have not addressed any of these specific issues regarding the Boyle et al. reference.

**Finally, Scholler et al. disclose immunization via the intradermal route, so the Boyle et al. reference is not germane to the instant rejection because the claims do not recite immunization via the im route and Scholler et al. disclose immunization via the intradermal route.**

Regarding applicants comments, Yokoyama-Kobayashi et al. teach **the identical vector recited in the claims** (see Figure 1(b) for a description of the peptide encoded by the vector and pages 162, sections 2.2,2.3 and page 163, section 3.2 for a description of said vector). Said vector encodes **a fusion protein containing an artificially added transmembrane domain wherein a protein is fused c-terminal to said transmembrane domain** (see abstract) and wherein the protein portion is therefore expressed extracellularly. Yokoyama-Kobayashi et al. disclose that said vector can be used to produce a fusion protein that can be used to anchor a secreted molecule to the cell surface (see abstract).

8. No claim is allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Schwadron, Ph.D. whose telephone number is 571 272-0851. The examiner can normally be reached on Monday-Thursday 7:30-6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Ron Schwadron, Ph.D.

Primary Examiner

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